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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,229	01/12/1999	GEOFFREY M. WAHL		7340

7590

06/10/2003

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/10/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,229

Applicant(s)

WAHL ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-27,31-50,53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 5-27,31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-39,42-50,53 and 54 is/are rejected.
- 7) ☒ Claim(s) 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed March 5, 2003 is acknowledged. Claims 33 were amended.

2. Claims 5-27, 31-50, 53 and 54 are pending.

Claims 5-27, 31, and 32, drawn to non-elected inventions, are withdrawn from consideration.

Claims 33-50, 53 and 54 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 33-36, 39-50, 53 and 54 under 35 U.S.C. 103(a) as being unpatentable over Hiraoka (Nature (1989) 342: 293-296) in view of Abken (Cancer Journal (1995) 8(3): 94-102) is withdrawn in view of applicant's arguments that neither of the references teaches a method where the cells express a labeled protein.

Claim Rejections Maintained and New Grounds of Rejection:

5. The rejection of claims 33-38, 42-50, 53 and 54 under 35 U.S.C. 103(a) as being unpatentable over Robinett (Journal of Cell Biology (1996) 135(6): 1685-1700) in view of Abken (Cancer Journal (1995) 8(3): 94-102) is maintained for the reasons of record.

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Applicant's arguments have been carefully considered, but are unpersuasive. Applicant argues that Robinett fails to teach methods where cells express a labeled protein that associates with chromosomes or double-minute chromosomes or extrachromosomal DNA. However, claim 50 is drawn to a method where the labeled protein is a lac repressor, which is the same protein that Robinett uses. Therefore, it appears that Robinett teaches the use of chromosome visualization using cells that express a labeled protein that is within the scope of the claims.

Claims 33-38, 42-50, 53 and 54 are drawn to methods to identify an agent that increases or decreases the amount of double minute chromosomes or extrachromosomal DNA in a cells comprising contacting the cell with the agent, wherein the cell expresses a labeled protein that associates with double minute chromosomes or extracellular DNA to form a labeled complex and comparing the amount of the labeled complex contained in the cell contacted with the agent with the amount of labeled complex contained in a cell that was not contacted with the agent. The labeled protein may be fluorescent protein fused to a protein that associates with DNA, where the fluorescent protein is Aequorea victoria green fluorescent protein.

Robinett teaches a method for visualizing chromosomes in Chinese Hamster Ovary (CHO) cells by transfecting cells with an expression vector containing DNA encoding a GFP-lac repressor-nuclear localization signal fusion protein (page 1687).

Abken teaches that extrachromosomal DNA and double minute DNA is chromosomal in origin and that double minute DNA can be eliminated from cancer cells by micronuclei formation in response to administration of various drugs. Abken also teaches that extrachromosomal DNA such as double minute DNA contains extra copies of oncogenes, which may cause the growth dysregulation of cancer cells.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to use the technique of chromosome visualization taught by Robinett to make a method for identifying other agents that induce micronuclei formation and thereby decrease the amount of double minute chromosomes. Alternatively, because the presence of double minutes is associated with carcinogenesis, it would be prima facie obvious to use the technique of Robinett to identify agents that increase the amount of double minute DNA or extrachromosomal DNA.

6. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is drawn to the method of claim 33, where the labeled protein that is expressed by the cell is a histone or a histone analog. The specification fails to provide a definition of histone analogs or to define the genus of histone analogs. Therefore, it is not clear which proteins would be considered a histone analogs, and which would not, rendering the scope of the claims indeterminate.

Conclusion

No claim is allowed. Claims 33-39 and 42-50, 53 and 54 are rejected. Claims 40 and 41 are objected to, because they depend from rejected claims. Claims 40 and 41 would be allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran

Patent Examiner

June 3, 2003


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